K113111

DEC - 8 2011

510(k) Summary

Inovo, Inc.

Date Prepared:	October 19, 2011
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Proprietary Names:	Chad Therapeutic Evolution Electronic Oxygen Conserver
Common Name:	Oxygen Conserver
Inovo Model Number	OM-900M
Classification Name:	Class II, 21 CFR 868.5905 Non Continuous Ventilator
Product Code:	NFB
Predicate Device Equivalence:	K103302 – Chad Therapeutic Evolution Model OM-900

Device Description:

The Inovo Evolution OM-900M is a microprocessor-controlled device, which is a combination of a oxygen pressure regulator and a oxygen conserver, designed for use with ambulatory oxygen systems. The built in oxygen regulator reduces the oxygen pressure from the oxygen cylinder to ensure proper operation of the oxygen conserving device. The low pressure oxygen enters the conserver portion of the device where the breath detection circuitry and inhalation sensors control the low pressure oxygen to deliver a precise amount of supplemental oxygen at a specific point in the breathing cycle. It delivers boluses of oxygen that is equivalent to 1 to 6 liters per minute depending on the user setting. The OM-900M is also able to detect motion via a 3 axis accelerometer. If motion is detected the software will automatically increase the oxygen delivery(active mode) to the patient. After motion has ceased, the software will then revert to the original rest setting(rest mode). The motion technology is taken from a previously cleared device Chad Sage Model TD-100 – K033364.

Intended Use:

The Chad Therapeutics Evolution Model OM-900M is intended for prescription use only, to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen up to 6 liters per minute, in their home and for ambulatory use.

Comparison of Device Technological Characteristics to Predicate Devices:

The submitted Inovo Evolution OM-900M has the following similarities to the predicate Inovo Evolution OM-900 and Sage TD-100

- Has the same intended use
- Incorporates the same basic modes and settings
- Incorporates similar materials
- Oxygen delivery method is fundamentally equivalent

Predicate Device Comparison

Table of Similarities and Differences

Description	Previously Cleared Device	Predicate Device	Modified Device
General Information			
Device Name	Chad Sage Model TD-100	Current Chad Evolution Model OM-900	Chad Evolution Model OM-900M
510(k) Number	K033364	K103392	Not yet assigned
Prescription device	Yes	Yes	Yes
Indications for use	The Chad Sage is intended for prescription use only, to be used as part of a portable therapeutic oxygen system for patients that require supplemental oxygen while at rest or during activity.	The device is intended for prescription use only, to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen up to 7 liters per minute, in their home and for ambulatory use.	Same as predicate device.
Contraindications	Not to be used for life support applications. In addition, it is not intended for use by patients who breathe more than 40 breaths of who consistently fail to trigger the device.	Not to be used for life support applications. In addition, it is not intended for use by patients who breathe more than 40 breaths of who consistently fail to trigger the device. It is not to be used while asleep.	Not to be used for life support applications. In addition, it is not intended for use by patients who breathe more than 40 breaths of who consistently fail to trigger the device. It is not to be used while asleep.
Patient population	Any patient for whom up to 6 lpm of supplemental oxygen has been prescribed.	Any patient for whom up to 7 lpm of supplemental oxygen has been prescribed.	Same as predicate device.
Environment	Home and ambulatory use	Home and ambulatory use	Same as primary predicate device.
Oxygen supply	Compressed oxygen cylinder 200 to 3000 psi	Compressed oxygen cylinder 500 to 3000 psi	Same as primary predicate device.
Specifications			
Weight in pounds (with batteries)	1.25 lbs	0.8 lbs	Same as primary predicate device
Dimensions (L x W x H) in inches	6.0in x 4.5in x 2.1	Approx. 6.1in x 3.1in x 2.7in	Same as primary predicate device
Device setting	1, 2, 3, 4, 5, 6	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6
Oxygen Bolus Size (ml)	• Setting 1: 10ml • Setting 2: 20ml • Setting 3: 30ml • Setting 4: 40ml • Setting 5: 50ml	• Setting 1: 10-15ml • Setting 2: 20-25ml • Setting 2.5: 25-30ml • Setting 3: 30-35ml • Setting 4: 40-50ml	• Setting 1: 10-15ml • Setting 2: 20-25ml • Setting 3: 30-35ml • Setting 4: 40-50ml • Setting 5: 50-60ml

	• Setting 6: 60ml	• Setting 5: 50-60ml • Setting 6: 60-75ml • Setting 7: 70-90ml	• Setting 6: 60-75ml
Pulse Frequency	Once every breath at all settings.	Once every breath at all settings.	Same as primary predicate device.
Continuous/Pulse Mode Switch	Yes.	Yes, ability to switch from pulsed to continuous flow set at 2lpm.	Same as primary predicate device.
Estimated Average Oxygen Savings	5:1	5:1	Same as primary predicate device.
Regulator Outlet Pressure	25 ± 5 psig	25 ± 5 psig	Same as primary predicate device.
		Technology	
Motion detection feature	Based on an accelerometer providing a signal to the microprocessor.	None.	Based on an accelerometer providing a signal to the microprocessor.
Keypad	Rest and Active Buttons.	One button. (Same button for Rest/Active)	Rest and Active Buttons.
Housing	Injection molded plastic enclosure.	Injection molded plastic enclosure.	Same as primary predicate device.
Microprocessor-controlled	Yes	Yes	Yes
Attached devices: Cannula	Single lumen cannula.	Standard single lumen cannula, 4ft to 7ft long	Same as primary predicate device.
Integral regulator body	All brass	Brass C36000 High-pressure components	Same as primary predicate device.
Oxygen Pressure Gauge	Yes.	Yes, 0 to 3000 psi	Same as primary predicate device.
Power	One 1.5 volt "C" size alkaline battery	Two 1.5 VDC Alkaline "AA-size" batteries	Same as primary predicate device

Statement of Safety and Effectiveness

Analysis of comparison of design, function and features of the Inovo Evolution OM-900M to the (K103302) Evolution OM-900, and (K033364) Sage TD-100, together with the results of testing demonstrates the device to be substantially equivalent to the predicate device in terms of meeting performances criteria and functioning as intended.

Non Clinical Verification

Software: The OM-900M software is the same as the OM-900 software with the addition of a motion detection algorithm. Possible new risks, such as the OM-900M does not respond to patient motion, were reviewed and documented in SP-206 Risk/Hazard Analysis, OM-900 SERIES Oxygen Conserving Device Revision C. The following verification activities were then performed:

Performed full Software Verification and Validation: PV-192 Software Verification & Validation Protocol For OM-900 Series Electronic Oxygen Conserving Device Revision E.

Updated Risk/Hazard Analysis: SP-206 Risk/Hazard Analysis, OM-900 SERIES Oxygen Conserving Device Revision C.
-Added Types of hazards and Intervening Mechanisms/Risk Reduction Methods to the Usability Hazard table.

Updated Software Design Description: SP-209 Software Design Description, Evolution OM-900 SERIES Oxygen Conserving Device Revision C.
-Added Descriptions/requirements that relate to the motion detection feature.

Updated Software Requirements: SP-210 Software Requirements Specification EVOLUTION OM-900 Series Electronic Oxygen Conserving Device Revision C.
-Added Descriptions/requirements that relate to the motion detection feature.

The OM-900M passed all tests as outlined in PV-192 Software Verification & Validation Protocol for OM-900 Series Electronic Oxygen Conserving Device Revision E.

Hardware: Motion Detection hardware was added to the OM-900 platform(creating the OM-900M). The additional hardware includes a turnkey accelerometer and an extra button on the user keypad. Possible new risks, such as the OM-900M does not respond to patient motion, were reviewed and documented in SP-206 Risk/Hazard Analysis, OM-900 SERIES Oxygen Conserving Device Revision C. The following verification activities were then performed:

Performed product validation to test new Motion Detection Hardware: PV-193 Product Validation OM-900 SERIES Evolution Oxygen Conserving Device Revision B.

Updated FMEA: SP-211, Failure Modes and Effects Analysis, EVOLUTION OM-900 Oxygen Conserving Device Revision C.
-Added Motion Detection hardware to "Critical Level Component Failures" list in Appendix A.

Updated Risk/Hazard Analysis: SP-206 Risk/Hazard Analysis, OM-900 SERIES Oxygen Conserving Device Revision C.
-Added Types of hazards and Intervening Mechanisms/Risk Reduction Methods to the Usability Hazard table.

Updated Engineering Requirements: SP-208 Engineering Specification, OM-900 SERIES Oxygen Conserving Device Revision C.
-Added Descriptions/requirements that relate to the motion detection feature.

The OM-900M passed all tests as outlined in PV-193 Product Validation OM-900 Series Evolution Oxygen Conserving Device Revision B. Results of these tests can be found in TR-202 VALIDATION, Evolution OM-900 SERIES OCD Revision B.

Conclusion

Based on the above, we conclude that the Inovo Evolution OM-900M Electronic Conserver is substantially equivalent to the predicate device listed and does not raise any new issues of safety and effectiveness. .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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DEC - 8 2011

Re: K113111
Trade/Device Name: Chad Therapeutics Evolution Model OM-900M
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NFB
Dated: November 28, 2011
Received: November 28, 2011

Dear Mr. Dildine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Chad Therapeutics Evolution Model OM-900M

Indications for Use: K113111

The Chad Therapeutics Evolution Model OM-900M is intended for prescription use only, to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen up to 6 liters per minute, in their home and for ambulatory use

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L. Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113111